# EXHIBIT 133

**From:** Barto, Bob
**To:** Tolen, Sue
**CC:** Connell, Jill
**Sent:** 10/2/2003 5:59:07 PM
**Subject:** Revised DEA Meeting minutes
**Attachments:** DEA minutes-3218.doc

Sue,

Thanks for pulling this together.

Bob

***Meeting Minutes***
***Endo/DEA Meeting***
***September 30, 2003***

DEA Attendees:

Kenneth Ronald, Special Assistant to Deputy Assistant Administrator
Frank Sapienza, Chief, Drug & Chemical Evaluation Section
Pat Good, Chief, Liaison and Policy Section
Vicki Seeger, Policy Section Officer
Betsy Willis, Chief, Drug Operations Section
Delores Williams Deputy Chief, Drug Operations Section
Christine Sannerud, Deputy Chief, Drug & Chemical Evaluation Section
Susan Carr, Drug Science Officer
Srihari Tella, Pharmacologist, Drug & Chemical Section

Endo Attendees:

Daniel Carbery, Group VP, Operations
George Stevenson, VP, Generic Business Unit
Jill Connell, Director, Supply Chain Management
Bob Barto, Director, Regulatory Affairs
Sue Tolen, Supply Chain Analyst

The meeting started with a welcome by Frank Sapienza of the DEA. Frank requested that the group introduce itself. Daniel Carbery began the Endo presentation with a brief overview of Endo. Prior to a presentation by George Stevenson, Frank Sapienza questioned whether Endo had a target date for the outcome of the pending litigation. Daniel Carbery responded that it could be any time from October through the end of the year.

George Stevenson presented the EN3218 Marketing Plan. During George's presentation the following questions were raised:

Q: *Why has MS Contin® taken so long to convert to generic?*
A: The technology in place at the time of the generic introduction (1998) is much different than the technology available today.

Q: *What does Endo mean by technology?*
A: The mechanism which allows the pharmacist to convert scripts from branded products to generics products (the computer system recognizes available generics).

Q: *Was our case to break the OxyContin® patent based on a different drug delivery method or formula?*
A: Our formula is different but still AB rated.

Bob Barto then proceeded with the Endo Risk Management Plan. During Bob's presentation the following questions were raised:

Q: *Who is Endo addressing its Risk Management Plans to at the FDA – the Office of Generic Drugs?*
A: The Endo Risk Management Plan as presented today, is applicable to all opioids marketed by Endo~~applies to all opioids, not just NDAs or ANDAs~~. We currently have a RMP under review at the Division of Anesthetic, Critical Care and Addiction Drug Products.

Q: *How did the 60,000 clinicians get added to the NIPC newsletter?*
A: ~~Reply cards,~~ Aattendance at an NIPC seminar, Business reply cards, through the Endo website.

Q: *Aren't there more than 60,000 physicians prescribing OxyContin®?*
A: ~~We don't know how to get to the rest of them.~~ Agreed, however we are only providing the material to those who request it. The distribution list is growing and one must realize that this is an on-going activity.

*Observation by Vicki Seeger that potentially some of the physicians simply wouldn't bother to participate in one of the CME sponsored events as they do not feel they need the training.*

Q: *Is the SOAP tool self-reporting of prior use or is it a psychological profile?*
A: The tool views information from several arenas, but is not geared solely at self-reporting of previous abuse.

Q: *Although completed by the patient(SOAP), is it still reviewed by the physician?*
A: Yes, the tool is primarily for the physician. However, ~~although~~ we have brochures on the same issue that are focused directly to the patient.

Q: *How will you look for or pick up diversion (at any level)*
A: We will monitor for signals of diversion but is difficult to predict what that signal will look like. Our intervention activities will be in response to the signals we detect. It is difficult, if not impossible, to state *a priori* what intervention we will undertake. However, Endo is committed to working with the DEA and law enforcement agencies as appropriate. Targeted educational activities will also be employed as appropriate.

Q: *Will you go out and look for data or will you only review data that comes to you?*
A: ~~We will go out and look for data~~ We will evaluate both internal and external databases (more detail will be discussed later in presentation).

Q: *Is ESRB comprised of only Endo personnel, or are their outside members?*
A: Yes, only Endo employees.

Q: *What type of safety signals will you look for?*
A: We won't know the signals until we generate and analyze some data. *(In general Endo informed the DEA that our Drug Safety/Pharmacovigilance group would be monitoring for adverse event reports of diversion, abuse, dependence, and overdose with the use of oxycodone extended release tablets ).*

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Q: *How can you determine which product is yours – many of these databases do not differentiate between products?*
A: The data can be analyzed using different grouping methods to determine if the signal can be separated out and attributed to any one specific product. Furthermore, this situation is inherent whenever you have multiple formulations of the active and generics in the marketplace.

Q: *Can you share pictures of your proposed product with law enforcement?*
A: Yes (pictures were shown and left with the DEA).

Q: *Do you anticipate that introduction of Oxycodone Extended Release tablets will increase the overall OxyContin® market?*
A: No, the market will remain the same, the generic product will just take a portion of the existing market.

Q: *There is some difference between OxyContin® and Oxycodone Extended Release – is there anything that would control diversion?*
A: No, the products are similar in key aspects; any differences would be in brands of excipients or such.

Q: *Will the cost of Oxycodone Extended Release tablets be significantly less?*
A: Our product should be 30-40% less, dependent on the number of generics entering the market.

Q: *If you win your case and Purdue seeks an appeal, will you have to wait to launch?*
A: No, but we would have to assess the strength of their appeal case as it would prove costly if they were to win on appeal.

Q: *If the generic product proves to be as problematic as the brand, how will Endo address it?*
A: Endo would work very closely with the DEA and FDA to be better than the reference product in its response.

Q: ***Are you sure you are ready to introduce this product? (Pat Good)***
A: We feel we have a strong background because of our history with Percocet, and we have employed strong consultants (former Federal Prosecutors) to guide our efforts and provide education.

Q: *How do you plan to get this education to the physicians who need it?*

A: Pain is becoming the 5th vital sign to be evaluated by physicians, ~~so~~ and therefore Endo~~we~~ plans ~~to provide more educational avenues~~on pursuing multiple channels for distributing our educational materials. *Recommendation from DEA that Endo should buy mailing lists of all practicing physicians/pharmacists who are prescribing/dispensing opioids and inform them of our materials.*

Q: *Do you check with IMS or some other service for high script levels?*
A: We can't answer that at present, but will check for you. ~~We have programs being developed by Medical Affairs.~~

Q: *Can you force physicians to take training?*
A: No

*Observation by Pat Good that there may be legitimate pain specialists scripting at the same level as a physician involved in diversion. The DEA is concerned that "Pain Specialists" are really illegitimate.*

Q: *Do you compile geographic data on disproportionate consumption?*
A: No, as our products generally go to central distribution.

Q: *Does Endo plan to issue a "Dear Doctor" letter, including educational brochures and supporting cautious use of product?*
A: While we do not currently have such a plan, we will investigate such a letter.

Q: *Do sales representatives "market" educational materials when doing physician visits?*
A: Our sales representatives will have the materials available. We will also follow up with physicians to assure that the salespeople have given the correct message. *(Note – this latter comment was mentioned in context of our oxymorphone detailing efforts. DEA was assured that no detailing of EN3218 would occur).*

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*Comment by Frank Sapienza: The "Early Warning Systems" are of no assistance; by the time the signal shows up in TESS or DAWN, it is too late.*

Q: *How is the product shipped from your contract manufacturers to the distributor and on to the pharmacy?*
A. We have the material shipped on dedicated trucks overnight to our distribution center in Memphis, TN which is run by UPS. UPS has an impressive security system, with some employees' actually undercover security agents. UPS will ship under similar methods currently employed for our Percocet products.

*Comment by Betsy Willis: we have seen a high rate of in-transit thefts.*

Q: *What do you do when you get a signal something is wrong?*

A: Change the way materials are shrink-wrapped or overpacked; change the way seals are applied to trucks; drop carrier with unacceptable breakage rates; change the way the product flows.

Q: *A number of states require special for the use of OxyContin® - will the same rules apply to Oxycodone Extended Release Tablets?*
A:

Q: *Have you performed a review of the medical need for Oxycodone Extended Release generic to assure that more physicians will not prescribe it because a generic is available?*
A: We believe sales will drop off as promotion of the brand slacks off.

Jill Connell then presented the EN3218 production timetable. During her presentation, the following questions were raised:

Q: *Your chart indicates that you will be requesting the balance of quota by October 15, but you will not have any sales numbers to provide?*
A: Yes, we need the balance of the quota to complete our preparations for a January launch.

*Comments by Frank Sapienza and Susan Carr: Please submit your additional quota letter now so we have the information as soon as possible.*

During the Question and Answer session, the following questions were raised:

Q: *We know that Mallinckrodt is your current supplier – do you have any plans to change suppliers in the near future?*
A: We may consider changing suppliers in the future to gain experience with a backup supplier.

Q: *With the entire quota you have already been granted and the balance you will be requesting – what will you do with the material if you lose the lawsuit?*
A: We will have the biggest witnessed burn in history.

*Closing comment by Frank Sapienza: Endo needs to react immediately to ANY signals detected and act quickly.*